Merck ignored Gardasil safety warnings from its own trial investigator

06/17/2026 // Cassie B. // **260** Views

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- Merck dismissed its own investigator's 2014 warning linking Gardasil to POTS without action or investigation.

- A Danish researcher testified that Merck refused to accept cases of POTS as adverse

events in Gardasil clinical trials.

- Denmark logged over 2,300 adverse event reports from 600,000 HPV-vaccinated women by 2016.

- Independent analysis found Merck excluded up to 90% of serious adverse events by using a 14-day reporting window.

- Gardasil generated 8.6 billion dollars in 2024 revenue while court documents reveal buried safety signals.

The pharmaceutical giant Merck received direct warnings about the Gardasil vaccine's link to a debilitating autonomic nervous system disorder from one of its own clinical trial investigators as early as December 2014 — and dismissed those warnings without investigation, according to recently unsealed court documents.

Dr. Jesper Mehlsen, a Danish clinical physiologist and former director of research at Frederiksberg Hospital in Copenhagen, served as the principal investigator in multiple Merck-sponsored clinical trials for Gardasil 4 and Gardasil 9. He later led one of five regional clinics established by the Danish government in response to what officials described as a "dramatic increase in post-Gardasil vaccination injuries."

Mehlsen's expert report, submitted as evidence in the *Robi v. Merck & Co.* lawsuit, reveals that he tried to alert the company to signs of autonomic dysfunction in patients after Gardasil vaccination. His concerns were met with indifference.

"Merck Denmark were receptive, but Merck USA, specifically Alain Luxembourg, discarded my concerns," Mehlsen stated in his testimony.

The report focuses on postural orthostatic tachycardia syndrome, or POTS, a condition in which the autonomic nervous system misfires, leaving patients struggling with dizziness, a racing heart, crushing fatigue, fainting and difficulty thinking clearly when upright. Mehlsen's team began seeing a cluster of similar cases in 2011, as young women who had recently received the HPV vaccine started arriving with overlapping complaints.

A pattern emerges but then gets buried

Mehlsen said he has personal knowledge that an investigator working under his supervision attempted to report cases of POTS in the Gardasil clinical trials, but Merck would not accept them as adverse events.

The flood of reports grew severe enough that by 2015 the Danish government had opened five regional centers dedicated to evaluating and treating affected patients. By 2016, the

Danish Medicines Agency had logged more than 2,300 adverse event reports from approximately 600,000 HPV-vaccinated women.

"The EMA ignored data provided by the WHO collaborating center in Uppsala, Sweden, and the subsequent safety concern with HPV vaccine as well as other reports linking Gardasil to these adverse events," Mehlsen wrote.

In his expert report, Mehlsen concluded: "Based on my education, experience, research, investigation, analyses, a review of the literature, and the material identified in this report, it is my opinion to a reasonable degree of medical and scientific certainty that Gardasil has been the probable cause of POTS and an autoimmune condition resembling myalgic encephalomyelitis (ME/CFS) and Post-COVID-19 syndrome."

Independent research dismissed

Dr. Peter C. Gøtzsche, a Danish researcher who submitted expert testimony in the same case, conducted a 350-page forensic analysis of Merck's clinical trial data. After reviewing 112,000 pages of regulatory documents, he concluded that Merck manipulated its data to such an extent that it would be "difficult if not impossible" for any independent scientist to accurately assess the vaccine's harms.

Gøtzsche found that Merck counted serious adverse events only if deemed vaccine-related by a study coordinator and only if they occurred within 14 days — a window that excluded up to 90% of adverse events, since autoimmune reactions can take weeks, months or years to emerge. He was particularly critical of the European Medicines Agency for accepting Merck's "contradictory, biased and misleading reports based on trials that were already flawed by design."

In vulnerable individuals, Mehlsen found that Gardasil's powerful immune activation appears to trigger a cascade in which the body's own antibodies turn against the autonomic nervous system. In his Danish cohort, 92% of patients reporting autoimmune side effects showed abnormal levels of these self-targeting antibodies.

Profits, settlements and unanswered questions

Jennifer Robi, a California woman confined to a wheelchair after receiving Gardasil, recently settled with Merck — one of more than 200 claimants resolved in a reported $50 million settlement that Merck stressed was not an admission of liability. The expert reports are now public.

Gardasil generated $8.6 billion in Merck's revenue in 2024, accounting for 13% of the company's total. Merck has set a target of $11 billion in annual Gardasil sales by 2030. With

that kind of money at stake, the question of whether safety signals were buried for the sake of the bottom line demands a serious answer.

Nearly two decades after Gardasil's global rollout, court documents reveal that the company's own investigator identified safety signals and was ignored. The question is not whether the truth will emerge, but how many young lives were affected while those warnings gathered dust.

Sources for this article include:

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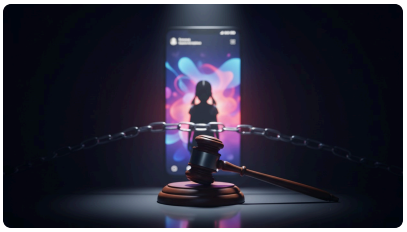

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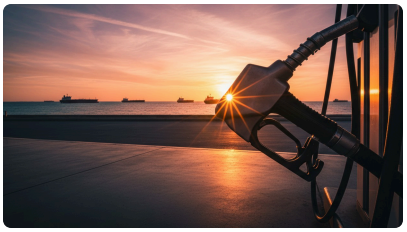

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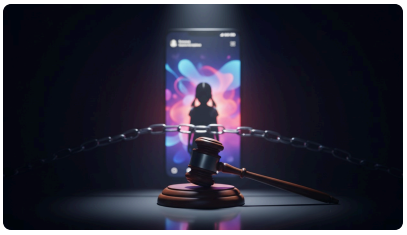

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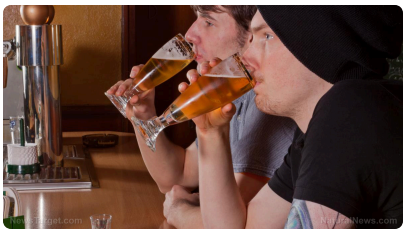

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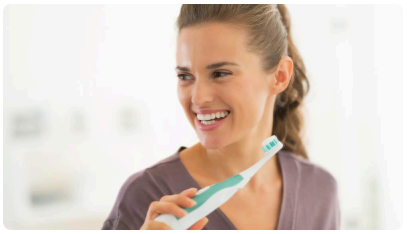

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